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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,225	06/30/2003	David Hung	005284.00198	1750

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EXAMINER	
SANG, HONG	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,225	HUNG ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,32-39 and 45-70* is/are pending in the application.

4a) Of the above claim(s) *8,10-12,16-18,32-39 and 45-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/30/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group II (Claim 9) with traverse in the reply filed on 5/30/06 and election of species of an estrogen antagonist on 7/19/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-7 and 13-18 are linking claims. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The information disclosure statement (IDS) filed on 6/30/03 has been considered. A signed copy is attached hereto.

4. Claims 1-18, 32-39 and 45-70 are pending. Claims 8, 10, 11, 12, 32-39 and 45-70 are withdrawn from further consideration as being drawn to non-elected inventions.

5. Because the references related to the invention of group I (claim 8) were retrieved while perform the prior art search for the inventions of group II. Group I and group II are rejoined here.

6. Claims 1-9 and 13-15 are under examination. Claims 16-18 are withdrawn from consideration as being drawn to non-elected species.

7. Due to species election, claims 1-9 and 13-15 are examined to the extent that the estrogen activity modulator is an estrogen antagonist.

Priority

8. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 112, 1st paragraph as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/117,281, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for claims 1-9 and 13-15 of this application. Claims 1-9 and 13-15 are

drawn to a method for identifying asymptomatic patients who have a likelihood of benefiting from the administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer. The provisional application no. 60/117,281 does not provide support for "asymptomatic patients", and "estrogen activity modulator" recited in claim 1. It only mentions "a patient" and "estrogen receptor modulator". Therefore, applicants are not entitled to the date of the provisional application no. 60/117,281.

If applicant believes that support for claims is present in the earliest filed priority document, applicant must, in responding to this action, point out with particularity, where such support may be found.

Specification

9. The first line of the specification should be updated if applicant desires priority under 35 U.S.C. 119(e), 120, 121 and 365(c) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application (s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No.___" should follow the filing date of the parent application. If a parent application has

become abandoned, the expression "now abandoned" should follow the filing date 6f the parent application.

For additional information, see United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003) "Benefit of Prior-Filed Application".

In the instance case, the parent application no 09/313,463 has become a patent. Applicants are required to update the first line of the specification.

10. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code see page 12, line 19, for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code found throughout the specification. See MPEP § 608.01.

Claim Objections

11. Claim 9 is objected to because of the following informalities: claim 9 is depend in part from a non-elected claim, i.e. claim 8. Appropriate correction is required.

12. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 recites "providing a ductal fluid sample from at least one duct of a breast of the patient". Claim 4 recites

"providing the ductal fluid sample comprises obtaining the sample from the breast". Therefore, claim 4 fails to further limit the subject matter of claim 1.

13. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 recites "examining the ductal fluid sample to determine the presence of precancerous or cancerous ductal epithelial cells". Claim 9 recites "wherein examining the ductal fluid comprises detection of an estrogen receptor in the ductal epithelial cells". Therefore, claim 9 fails to further limit the subject matter of claim 1.

Claim Rejections - 35 USC § 112, 2nd paragraph

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is indefinite because the last part of the claim does not correlate completely with the preamble which states "a method for identifying asymptomatic patients who have a likelihood of benefiting from the administration of an estrogen

activity modulator for risk reduction or therapeutic treatment of breast cancer". The phrase "or therapeutic treatment of breast cancer" is missing at the end of the claim.

B. Claim 5 is indefinite because it is unclear whether the sample is obtained from the same patient or from any patient or subject.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1-4, 8, 9 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Fabian et al. (J. Cell Biochem., 1993, 17G: 153-160, IDS).

Claims 1-4, 8 and 13-15 are interpreted as a method for identifying asymptomatic patients who have a likelihood of benefiting from the administration of an estrogen antagonist for risk reduction or therapeutic treatment of breast cancer, said method comprising: providing a ductal fluid sample from at least one duct of a breast of the patient; and examining the ductal fluid sample to determine the presence of precancerous or cancerous ductal epithelial cells, wherein patients determined to have the presence of either precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen antagonist or therapeutic treatment of breast cancer. Claims are further limited wherein the precancerous ductal epithelial

cells comprise cells at a stage selected from the group consisting of ductal hyperplasia, atypical ductal hyperplasia, and low grade ductal carcinoma in situ (LG-DCIS, the cancerous ductal epithelial cells comprise cells at a stage selected from the group consisting of high grade ductal carcinoma in situ (HG-DCIS) and invasive carcinoma, examining the ductal fluid comprises cytological examination of ductal epithelial cells in the sample to determine whether they are precancerous or cancerous, the asymptomatic patients comprise patients in a high risk group for breast cancer selected from the group consisting of patients with a family history of breast cancer, patients of increasing age, patients having one high risk parity factor, patients having high risk gene status, patients having at least one previous breast biopsy, patients having a previous diagnosis of breast cancer, and patients having any other risk factor for breast cancer, the asymptomatic patients comprise patients selected from a group consisting of patients who are negative in a standard cancer test and patients with inconclusive or ambiguous results from a standard cancer test.

Claim 9 is interpreted as a method of claim 1, further comprising detection of an estrogen receptor in the ductal epithelial cells

Fabian et al. teach a method of providing and cytologically examining ductal fluid obtained via fine needle aspiration from high and low risk of women, wherein high risk women include those with a first-degree relative with breast cancer, prior node-negative breast cancer, precancerous mastopathy (atypical hyperplasia or carcinoma in situ), and low-risk women include none of the above risk factors, nor a prior breast biopsy or clinical evidence of fibrocystic disease (see abstract). Fabian et al. teach that the

needle was placed almost perpendicular to the chest wall and tissue behind nipple was probed deeply in an attempt to sample the terminal ducts (see page 154, 1st paragraph under METHODS). Fabian et al. teach that the ductal epithelial cells are examined cytologically and cancer markers including the estrogen receptor are determined (see page 154, right column). Fabian et al. teach that aspirates are classified cytologically as normal, apocrine metaplasia, epithelial hyperplasia, or dysplasia (see abstract, and page 154, right column, 2nd paragraph). Fabian et al. teach that the difference in the prevalence of multiple biomarker abnormalities among various cytologic categories were statistically significant (p-0.02) (see abstract). Fabian et al. teach that the increased prevalence of single and multiple biomarker abnormalities with increase cytologic abnormalities indicates that one or more of these biological markers may be potentially useful in predicting who will be at highest risk for breast cancer development within a 5-10 year time frame (see last paragraph).

Because Fabian teaches all the active steps of the claimed method, the method of Fabian would be capable of identifying patients who have a likelihood benefiting from the administration of an estrogen antagonist for risk reduction or therapeutic treatment of breast cancer. Moreover, the last part of claim 1, i.e. "wherein patients determined to have the presence of either precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity" is also not given patentable weight because the word "wherein" is not an actual method step and can indicate a mental process or be inherent results of the method.

18. Claims 1-6, 8 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Sauter et al. (British J. Cancer, 1997, 76(4): 494-501, IDS).

Claims 1-4 and 13-15 are set forth above (see paragraph 15 above).

Claims 5-6 are drawn to method of claim 1, wherein providing the ductal fluid sample comprises receiving a sample which had been previously obtained, the fluid was obtained by nipple aspiration of the milk ducts or by ductal lavage of at least one breast milk duct.

Sauter et al. teach a non-invasive method for early detection of breast cancer comprising collecting nipple aspirate fluid from a patient, cytologically analyzing the fluid (e.g. computerized image analysis of nipple aspirate fluid epithelial cells), and evaluating the promising cancer markers, wherein said patients were categorized by their risk for breast cancer as having no risk factors, a first degree relative with breast cancer, a history of curative treatment for ductal carcinoma in situ (DCIS), or invasive breast cancer, precancerous mastopathy (atypical hyperplasia (AH) or lobular carcinoma in situ (LCIS) or recently diagnosed invasive cancer of the breast (see abstract and page 495, left column, 2nd paragraph). Sauter et al. teach that the nipple aspirate fluid (NAF) was collected and transported to the cytology laboratory for processing (see page 495, right column, 2nd paragraph), which meet the specific embodiment of claim 5). Sauter et al. teach that three of the slides were used for cytological examination, and each specimen was designated as containing scant, benign, atypical or malignant cells (see page 496, left column). Sauter et al. teach that the nipple aspirate fluid cytology correlated with increased breast cancer risk (P=0.002)

(see abstract). Sauter et al. teach that biomarkers identified in nipple aspirate fluid may prove useful either as an adjunct to currently accepted breast cancer screening methods, or to evaluate response to a chemopreventive agent (see abstract).

Because Sauter teaches all the active steps of the claimed method, the method of Sauter would be capable of identifying patients who have a likelihood benefiting from the administration of an estrogen antagonist for risk reduction or therapeutic treatment of breast cancer. Moreover, the last sentence of claim 1, i.e. "wherein patients determined to have the presence of either precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity" is also not given patentable weight because the word "wherein" is not an actual method step and can indicate a mental process or be inherent results of the method.

19. Claims 1-4, 6-8 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by JAMA (JAMA, 1973, 224 (6): 823-827) in view of Sauter et al. (British J. Cancer, 1997, 76(4): 494-501, IDS).

Claims 1-4, 6-8 and 13-15 are set forth above (see paragraphs 17 and 18 above).

Claim 7 is drawn to method of claim 1, wherein the fluid collected is from a single duct.

The JAMA reference teaches a method for early detection of breast cancer in a patient comprising a) removing fluid through nipples with a suction device or by a method comprising inserting hair-like catheters into breast ducts with the help of an

operating microscope, flushing the ducts with saline for cell studies; and b) examining the fluid to identify abnormal cells (see page 825, left column, 3rd and 4th paragraph, and page 826, right column, 3rd paragraph). The patients having abnormal cells include hyperplasia, chronic mastitis, intraductal papillomas, and severe dysplasis (the cells of these women could be considered pre-malignant), carcinomas including invasive carcinoma (see page 826, right column, 3rd and 4th paragraph). The patients that were diagnosed carcinoma appeared asymptomatic (see page 326, right column, 5th paragraph). JAMA reference teaches that the breast fluid from each duct is examined separately (see page 827, left column, 3rd paragraph). The JAMA reference teaches that women who are thought to be at high risk for breast cancer are examined this way every six month (see page 827, 4th paragraph). The JAMA reference teaches that the fluids are tested for reverse transcriptase, an enzyme that has been implicated as a possible cancer marker (page 827, left column, 5th paragraph). The JAMA reference discloses using said method to study of breast fluid from patients without signs of breast disease, undetermined breast lesions, at high risk and with clinical evidence of breast cancer (see page 827, right column, last paragraph).

While JAMA does not explicitly teach that the abnormal cells in the ductal fluid are epithelial cells, the abnormal cells in ductal fluid encompass exfoliated breast epithelial cells as evidenced by Sauter et al. Sauter et al. teach that the ductal fluid contains several types of cells, including exfoliated breast epithelial cells (see page 498, right column, 3rd paragraph).

Because JAMA teaches all the active steps of the claimed method, the method of JAMA would be capable of identifying patients who have a likelihood benefiting from the administration of an estrogen antagonist for risk reduction or therapeutic treatment of breast cancer. Moreover, the last sentence of claim 1, i.e. "wherein patients determined to have the presence of either precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity" is also not given patentable weight because the word "wherein" is not an actual method step and can indicate a mental process or be inherent results of the method.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1-8, and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 13, 15 and 19-21 of U.S. Patent No. 6,610,484B1. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The interpretation of claims 1-8 and 15 is set forth above (see paragraphs 17-19 above).

Claims 1 and 9 of U.S. Patent No. 6,610,484B1 is drawn to a method for identifying a patient having breast cancer or breast precancer, said method comprising: placing a ductal access tool comprising a single lumen in a breast duct of a patient, wherein the single lumen has an inner diameter large enough to retrieve clusters of greater than 10 cells; infusing a fluid into the duct through the single lumen, infusing a fluid into the duct through the single lumen; retrieving a ductal fluid sample from the accessed duct through the single lumen, wherein the ductal fluid sample comprises ductal epithelial cells and is free of ductal fluid from any other duct of the breast; and examining the ductal fluid sample to determine the presence of a marker comprising a protein, a polypeptide, a nucleic acid, a polynucleotide, an mRNA, a small organic molecule, a lipid, a fat, a glycoprotein, a glycopeptide, a carbohydrate, an oligosaccharide, a chromosomal abnormality, a whole cell having a marker molecule, a particle, a secreted molecule, an intracellular molecule, and a complex of a plurality of molecules, wherein the method further comprising analyzing the cells in the ductal fluid sample for abnormal cytology. Claims 13, 15 and 19-21 of U.S. Patent No. 6,610,484B1 is drawn to a method of identifying a patient suspected of having breast

cancer or breast precancer, said method comprising: examining a ductal fluid sample to determine the presence of a cancer or precancer marker comprising a protein, a polypeptide, a peptide, a nucleic acid, a polynucleotide, an mRNA, a small organic molecule, a lipid, a fat, a glycoprotein, a glycopeptide, a carbohydrate, an oligosaccharide, a chromosomal abnormality, a whole cell having a marker molecule, a particle, a secreted molecule, an intracellular molecule, and a complex of a plurality of molecules, wherein the fluid sample is obtained by a method comprising the steps of: (a) placing a ductal access tool comprising a single lumen in a breast duct of a patient, wherein the single lumen has an inner diameter large enough to retrieve clusters of greater than 10 cells; (b) infusing a fluid into the duct through the single lumen; and (c) retrieving the ductal fluid sample from the accessed duct through the single lumen, wherein the fluid sample comprises ductal epithelial cells and is free of ductal fluid from any other duct of the breast; wherein the presence of the marker in the ductal fluid sample identifies a cytological category selected from the group consisting of normal, abnormal, hyperplasia, atypical ductal carcinoma, ductal carcinoma in situ (DCIS), ductal carcinoma in situ--low grade (DCIS-LG), ductal carcinoma in situ--high grade DCIS-HG), invasive carcinoma, atypical mild changes, atypical marked changes, and atypical ductal hyperplasia (ADH), wherein the ductal fluid sample comprises ductal epithelial cells, the cytological category is ductal carcinoma in situ--low grade (DCIS-LG), ductal carcinoma in situ--high grade (DCIS-HG), invasive carcinoma.

Because claims 1, 9, 13, 15 and 19-21 of U.S. Patent No. 6,610,484B1 teach each of the active steps of the instantly claimed method, the methods of claims 1, 9, 13,

15 and 19-21 of U.S. Patent No. 6,610,484B1 would be capable of identifying patients who have a likelihood benefiting from the administration of an estrogen antagonist for risk reduction or therapeutic treatment of breast cancer. Moreover, the last sentence of the instant claim 1, i.e. "wherein patients determined to have the presence of either precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity" is also not given patentable weight because the word "wherein" is not an actual method step and can indicate a mental process or be inherent results of the method.

Claims 1-8 and 15 are directed to an invention not patentably distinct from claims 1, 9, 13, 15 and 19-21 of commonly assigned U.S. Patent No. 6,610,484B1 for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 6,610,484B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

22. Claims 1, 4, 6-8, and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 11, 13 and 22 of U.S. Patent No. 6,642,009B2. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The interpretation of claims 1, 4, 6-8 and 15 is set forth above (see paragraphs 17-19 above).

Claims 1, 2 and 11 of U.S. Patent No. 6,642,009B2 are drawn to a method to aid in diagnosing breast cancer or pre-cancer comprising: placing a ductal access tool comprising a single lumen in a breast duct of a patient, wherein the single lumen has an inner diameter large enough to retrieve clusters of greater than 10 cells; infusing a fluid into the duct through the single lumen; and retrieving a ductal fluid sample from the accessed duct through the single lumen, wherein the ductal fluid sample comprises ductal epithelial cells and is free of ductal fluid from any other duct of the breast, wherein the method further comprising: examining the ductal fluid sample to determine the presence or absence of a marker, the method further comprising analyzing collected ductal epithelial cells by cytology. Claims 13 and 22 of U.S. Patent No. 6,642,009B2 are drawn to a method for analyzing breast markers or epithelial cells, comprising:

placing a ductal access tool comprising a single lumen in a breast duct of a patient, wherein the single lumen has an inner diameter large enough to retrieve clusters of greater than 10 cells; infusing a fluid into the duct through the single lumen; retrieving a ductal fluid sample from the accessed duct through the single lumen, wherein the ductal fluid sample comprises ductal epithelial cells and is free of ductal fluid from any other duct of the breast; and determining the presence or absence of a marker in the ductal fluid sample, wherein the marker determined is cytology of ductal epithelial cells.

Because claims 1, 2, 11, 13 and 22 of U.S. Patent No. 6,642,009B2 teach all the active steps of the instantly claimed method. The method of claims 1, 2, 11, 13 and 22 of U.S. Patent No. 6,642,009B2 would be capable of identifying patients who have a likelihood benefiting from the administration of an estrogen antagonist for risk reduction or therapeutic treatment of breast cancer. Moreover, the last sentence of claim 1, i.e. "wherein patients determined to have the presence of either precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity" is also not given patentable weight because the word "wherein" is not an actual method step and can indicate a mental process or be inherent results of the method.

Claims 1, 4, 6-8 and 15 are directed to an invention not patentably distinct from 1, 2, 11, 13 and 22 of commonly assigned U.S. Patent No. 6,642,009B2 for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 6,642,009B2, discussed above,

would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

23. No claims are allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1643
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